POC approved 4/2/08 Lmethell HB

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	NVN1888ASC	A. BUILDING _____ B. WING _____	03/13/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LAKE TAHOE SURGERY CENTER	212 ELKS POINT RD #201 ZEPHYR COVE, NV 89448

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 00	INITIAL COMMENTS This Statement of Deficiencies was generated as a result of a Focused State Licensure Survey conducted at your facility on 3/13/08. The survey was conducted using Nevada Administrative Code (NAC) 449, Surgical Centers for Ambulatory Patients. Findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigations, actions, or other claims for relief that may be available to any party under applicable federal, state, or local laws. The following regulatory deficiencies were identified.	A 00	RECEIVED APR 01 2008 BUREAU OF LICENSURE AND CERTIFICATION CARSON CITY, NEVADA	
A 10	NAC 449.980 Administration The governing body shall ensure that: 7. The center adopts, enforces and annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organization chart. These policies and procedures must: (a) Be approved annually by the governing body. This Regulation is not met as evidenced by: Based on observations, interview and record review on 3/13/08, the governing body did not enforce its policies and procedures regarding infection control and the sterilization of instruments. Findings include: The facility was initially toured at 8:00AM. The	A 10	A-10-Door stops a) Corrective action was accomplished by removing all doorstops and sandbags from area on 3/13/08. O.R. doors were closed on 3/13/08 and remain closed with the exception of when there is movement of personnel or equipment. b) Identification of others having potential to be affected: we had 2 individuals make 2 sweeps of the area on 3/13/08 to determine that no doorstops or sandbags remained in the area. c) Systematic changes include providing all clinical staff with a summary of the regulations and the purpose attached to a copy of the "Traffic Control" and Environmental Sanitation in the OR policies and having them sign a receipt/compliance acknowledgement form. These will be placed in the employee's files (see sample form-Attachment A) d) Corrective action will be monitored by daily environmental round checks beginning 3/25/08 (see Attachment B).	3/13/08 3/13/08 3/25/08

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Kathy Cerskus TITLE VP of Operations (X6) DATE 3/31/08

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A 10	Continued From page 1 facility had three operating rooms. Operating Room (OR) #1 was being used for storage. The door to that OR was closed and remained closed for the entire day. Operating Room #2 was to be used for surgical cases the day of the survey. The door to that OR was propped open with a sand bag until 8:30AM. Staff removed the sand bag when they brought sterile supplies into the room for the first case of the day The door was observed propped open again from 11:13 AM to 11:20AM after the first patient was taken to the recovery room. Operating Room #3 was not being used for surgical cases for the day of the survey. The door to that OR was propped open with a sand bag until a staff person removed the sand bag at 9:50AM. Two facility policies titled "Traffic Control" and "Environmental Sanitation in the OR" were reviewed. The two policies indicated that operating room doors should be kept closed except when personnel are entering or exiting. A staff nurse reported the facility followed the practices of the Association of Operating Room Nurses (AORN). AORN 2006 Standards, Recommended Practices, and Guidelines regarding operating room doors revealed that doors to the operating rooms should be closed except during movement of patients, personnel, supplies and equipment. The air pressure within each operating room should be greater than in the semirestricted area to prevent airborne contamination. Positive pressure within the operating room can not be maintained if the doors are kept open. A staff person reported they kept the doors open so they could easily locate each other.	A 10	Disciplinary action of non-compliant employees will be done if indicated. The rounding form will be kept for 3 years e) Responsible party for monitoring compliance is LTSC Administrator f) Date of correction was 3/13/08	3/13/08

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A 10	Continued From page 2 In the room where clean instruments were assembled and wrapped, a piece of paper titled, "Sterile Processing Rules and Procedures" was observed taped to the wall. The rules indicated that all autoclave printouts needed to be initialed after each load was run and the flash autoclave contents needed to be labeled on the printout. A policy titled, "Sterilization Process of Autoclaves" was reviewed. The policy indicated that personnel should initial autoclave graph paper when removing items from the autoclave to make sure items were properly sterilized. The facility was equipped with two autoclaves. The printouts for both autoclaves were reviewed. No initials were observed on the printouts. The printout of the flash autoclave was not labeled with the contents of each load. The surgical technician reported he was so busy that he neglected to initial the printouts after each load was run. The technician also reported that he was writing the load contents of the flash autoclave in a log book and was not aware he had to write the load contents on the printout too. In the room where the Steris unit was located, a piece of paper titled, "To Run a Steris Cycle" was observed taped to the wall. The notice indicated the patient identification number and the condition of the chemical strip were to be written on the printout. The policy titled, "Sterilization Process of Autoclaves" revealed that personnel were to initial the printout when removing items from the Steris unit. The Steris unit printouts were reviewed dating	A 10	A-10-Autoclave Labeling a) Scrub Technician 1, was educated by surveyors at the time of the survey 3/13/08. From that period on, all autoclave and Steris printouts were initialed after each load was run. The condition of the chemical indicator strips were confirmed that adequate exposure was reached, and verification that the parameters were met was confirmed on the Steris machine printout. Notation of the patient identification number was also made to the Steris printout. The flash autoclave contents were listed in the autoclave logbook, and verification that the exposure parameters were met was confirmed on the autoclave printout. All staff members are initialing the autoclave printout for each load run in the machine. b) All other Lake Tahoe Surgery Center (LTSC) personnel that will be doing instrument processing will have the policy and procedure reviewed and will demonstrate competency on following the labeling directions. c) Support Tech 1, a 20 year Barton Healthcare System (BHS) Surgery Department employee with extensive Instrument Processing experience (see documents faxed to DHHS 3/14/08) came to LTSC 3/14/08. He spent 5 hours with Scrub Tech 1 reviewing all instrument processing and sterilization policies and the importance of thorough, accurate documentation. Samples of logs from BHS were shared and some were implemented at LTSC. Support Tech 1 returned to LTSC 3/19/08 along with Clinical Systems Administrator from BHS with more than 30 years of surgical experience. They reviewed Scrub Tech 1's Steris and autoclave logs and strips. Recommendations were made to pre-write all dates in the log for the month and make notations daily so that tracking was very clear to follow. Support Tech 1 and Clinical Systems Admin. ran biological tests for both autoclaves and the Steris machine. New Support Tech employee 2 was included in the education and demonstrations. On 3/21/08 Scrub Tech 1 & Support Tech 2 spent the day in the BHS Reprocessing Department.	3/13/08 3/14/08 3/19/08 3/21/08

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A 10	Continued From page 3 back to 2/22/08. The printouts were not initialed, the patient identification numbers were not written down and the condition of the chemical strips were not written down. The surgical technician reported he was putting a chemical indicator in the tray and looking at the printout, but was not aware he was to write the above mentioned information down on the Steris printouts. Two policies titled, "Processing of Sterile Supplies" and "Sterilization Process" were reviewed. Both policies indicated that all jointed instruments were to be opened or unlocked during the sterilization process. AORN 2006 Standards, Recommended Practices, and Guidelines regarding sterilization indicated that instruments should be held in an opened and unlocked position. Fifteen sterile packages (or peel packs) of assorted types of clamps and needle drivers were inspected. The instruments inside of twelve sterile packages were clamped closed which did not allow the steam to penetrate and fully sterilize the instruments. Two large instrument trays awaiting sterilization were inspected. The clamps and assorted instruments were strung on a metal stringer allowing the lock boxes to be open during the steam sterilization process. The surgical technician reported he knew instruments on trays were held open by metal stringers, but he was not aware that instruments sterilized in peel packs needed to be opened. Severity: 2 Scope: 3	A 10	Steris loads were run; biological testing was explained and ready readout testing was accomplished. Return demonstrations were done to a Reprocessing day-shift employee's satisfaction. It was identified that an individual with more instrument processing technician experience was needed for LTSC. A job description was written (see Attachment C). An interview was conducted with an individual with 16 years Experience. She will be offered a position by 3/28/08. She will be oriented in the BHS Reprocessing Department before she works at LTSC. She will oversee this area once she is oriented in the BHS Reprocessing Department.	3/26/08
			d) Corrective actions will be monitored by daily environmental round checks beginning 3/25/08. The daily logs will be kept for 3 years. Disciplinary action of non-compliant employees will be done if indicated.	3/25/08
			e) Responsible party for monitoring compliance is LTSC Administrator.	
			f) Anticipated date of correction is 3/21/08 after the completion of Scrub Tech 1 and Support Tech 2 BHS training	3/21/08
			A-10- unclamping instruments in peel packs a) On 3/14/08, all instruments in peel packs were inspected. Any that were clamped were opened, unclamped, rewrapped and resterilized. During the surveyor's visit, scrub tech 1 verbalized understanding of this sterilization principle.	3/14/08
			b) On 3/19/08, Support Tech 1 inspected the entire area to determine that all instruments had been sterilized appropriately.	3/19/08
			c) On 3/19/08, Support Tech 1 again explained the sterilization principles to Scrub Tech 1. He also instructed Scrub Tech 1 about the consistent labeling of all peel packs to include, the autoclave #, date of sterilization, load # and processing tech's initials. This was reiterated by BHS staff when Scrub Tech 1 & Support Tech 2 spent 3/21/08 in BHS Reprocessing Depart.	3/19/08 3/21/08
			d) Corrective actions will be monitored by daily environmental round checks beginning 3/25/08. The daily logs will be kept for 3 yrs. Disciplinary action of non-compliant employees will be done if indicated.	3/25/08
			e) Responsible party for monitoring compliance	

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	Continued From page 4		LTSC Administrator f) Date of correction was 3/14/08	3/14/08
A 94	NAC 449.983 Protection from Fires and Other Disasters 1. The administrator shall ensure that the center, members of the staff and patients are adequately protected from fire or other disasters. He shall prepare a written plan describing all actions to be taken by the members of the staff and patients in the case of any such incident. This plan must be approved by the governing body and the local fire department and must include provisions for: (a) Evacuation routes and procedures that are posted in the center. This Regulation is not met as evidenced by: National Fire Protection Association (NFPA) 101 Life Safety Code Chapter 21 Existing Ambulatory Health Care Occupancies. 21.1.1.4 Additions, Conversions, Modernization, Renovation, and Construction Operations. 21.1.1.4.1.3 Doors shall be permitted to be held open if they meet the requirements of 21.2.2.3. 21.2.2.3 Any door required to be self-closing shall be permitted to be held open only by an automatic release device that complies with 7.2.1.8.2. Based on observation on 3/13/08, the administrator did not protect staff and patients from fire. Findings include: The facility was initially toured at 8:00AM. Doors that are not equipped with automatic release devices are not allowed to be held open by any	A 94	A-94- Protection from Fire a) Corrective action was accomplished by removing all doorstops from areas identified on 3/13/08. Doors remain closed. A work order was completed to have the door in Private Recovery Room #2 fixed so that it closed all of the way. b) Identification of others having potential to be affected: we had 2 individuals make 2 sweeps of the area on 3/13/08 to determine that no doorstops remained in the area. c) Systematic changes include providing all clinical staff with a summary of the regulations and the purpose attached to a copy of the "Traffic Control" and Environmental Sanitation in the OR policies and having them sign a receipt/compliance acknowledgement form. These will be placed in the employee's files (see sample form-Attachment A) The rounding form will be kept for 3 years. Door on Private Recovery Room #2 was fixed on 3/20/08 by BHS Engineer (see Attachment D) d) Corrective action will be monitored by daily environmental round checks beginning 3/24/08. The rounding form will be kept for 3 years Disciplinary action of non-compliant employees will be done if indicated. e) Responsible party for monitoring compliance is LTSC Administrator f) Anticipated date of correction is 3/28/08	3/13/08 3/13/08 3/20/08 3/24/08

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A 94	Continued From page 5 method. The following doors were not equipped with automatic release devices and were observed to be propped open with rubber door stoppers: 1. Soiled utility room 2. Clean utility room 3. Sterile instrument room 4. Storage 5. Sterilization room 6. Staff lounge 7. Private recovery room #1 8. Private recovery room #2 Each door was labeled as a "listed 20 minute fire door." When the propped open fire doors were brought to the attention of a staff nurse at 9:50AM, she closed all the doors. The door to the Private Recovery Room #2 did not close all the way due to the height of the carpet. A staff person reported they kept all the doors open so they could hear equipment alarms and to easily locate each other throughout the facility. Severity: 2 Scope: 3	A 94		
A152	NAC 449.9895 Sterilization 2. If these materials are sterilized on the premises, the process of sterilization must be supervised by a person who has received specialized training in the operation of that process, including training in methods of testing to verify the efficiency of the process. This Regulation is not met as evidenced by: Based on personnel record review and staff interview on 3/13/08, it was determined that the facility failed to demonstrate that staff were trained and qualified to be in a position of instrument technician.	A152	A 152- Sterilization training a) Corrective action was accomplished by bringing 20+ year Instrument Processing Technician from BHS and OR Clinical Systems Administrator from BHS with more than 30 years of surgical experience to LTSC on 3/13/08. They reviewed procedures with Scrub Tech 1. b) The facility identified that new employee & Support Tech 2 could be affected by the same deficient process. He was included in follow-training that occurred 3/19, 3/21, and 3/26/08. c) Support Tech 1, a 20 year BHS Surgery Dept. employee with extensive Instrument Processing experience (see documents faxed to DHHS 3/14/08)	3/13/08

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A152	Continued From page 6 Findings include: Initial tour and observation of the facility revealed that the surgical technician was responsible for cleaning and sterilizing all of the instruments required for surgical procedures. He was also responsible for all tests to ensure proper sterilization. A review of the surgical technician's personnel record revealed that he had been an employee of the facility since 8/8/01. An orientation checklist was completed on 8/10/01. This checklist indicated that this employee received all his new employee orientation on the one day. An entry " STERIS " was part of this orientation, but it does not include any specifics of what was taught. There was no evidence of any instruction on the use of the autoclaves, testing for sterilization maintenance or logging reports of machine maintenance. A clinical skills checklist was completed by the operating room manager on 7/21/04. This skills check list did not include any skill evaluations of monitoring autoclaves and sterilizers for biological testings. A current job description signed 10/5/06 acknowledged this employee as a surgical technologist. Some of the duties and responsibilities included: - Demonstrates ability to understand and use autoclaves, sonic cleaner and rinser/dryer, Steris Cycle 1, but there was no evidence of training for performing biological tests of the autoclaves and Steris machines. An interview with the employee revealed that he was not signing the tapes for the autoclaves. He	A152	came to LTSC 3/14/08. He spent 5 hours with Scrub Tech 1, reviewing all instrument processing and sterilization policies and the importance of thorough, accurate documentation. Samples of logs from BHS were shared and some were implemented at LTSC. Support Tech 1 returned to LTSC on 3/19/08 along with OR Clinical Systems Administrator with more than 30 years of surgical experience. They reviewed Scrub Tech 1's Steris and autoclave logs and strips. Recommendations were made to pre-write all dates in the log for the month and make notations daily so that tracking was very clear to follow. Support Tech 1 & OR Clincal System Administrator ran autoclave and Steris machine biological tests. New Support Tech 2 employee,was included in the education and demonstrations. On 3/21/08, Scrub Tech 1 & Support Tech 2 spent the day in the BHS Reprocessing Department. Steris loads were run; biological testing was explained and ready readout testing was accomplished. Return demonstrations were done to Reprocessing day shift employee's satisfaction. On 3/26/08, new employee was hired as an Instrument Processing Technician for LTSC. She has 14 years of Instrument Processing Technician experience. She will oversee this area once she is oriented in the BHS Reprocessing Department. On 3/26/08, Steris service representative gave a LTSC staff in-service on the proper use of the autoclaves and Steris machine, and routine testing and maintaining biological tests, as well as record-keeping requirements (see Attachment G) d) Corrective actions will be monitored by daily environmental round checks beginning 3/25/08. The daily logs will be kept for 3 years. Disciplinary action of non-compliant employees will be done if indicated. e) Responsible party for monitoring compliance is LTSC Administrator.	3/19/08 3/21/08 3/26/08 3/26/08 3/25/08

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A152	Continued From page 7 stated that he was not aware that he should. He stated that he did not know anything about maintaining biological tests for the Steris machines, and was not aware of any log book. He acknowledged that he did not know what the incubator looked like that was used to perform the biological tests. There was no evidence that he had been provided any training to equip him with the knowledge necessary to perform his new duties. Severity: 2 Scope: 3	A152	f) Anticipated date of correction is 3/28/08 after the completion of Scrub Tech 1 and Support Tech 2 BHS and in-service training.	
A154	NAC 449.9895 Sterilization 4. The efficiency of the method of sterilization used must be checked not less frequently than once each month by bacteriological tests. Records of the results of these tests must be maintained by the center for at least 1 year. This Regulation is not met as evidenced by: Based on observation, record review and interviews on 3/13/08, the facility did not test the efficiency of the steam sterilization system from 3/4/08 to 3/13/08 and the efficiency of the Steris sterilization system from 2/22/08 to 3/13/08. Findings include: In the room where clean instruments were assembled and wrapped, a piece of paper titled, "Sterile Processing Rules and Procedures" was observed taped to the wall. The rules indicated that biological tests were to be performed on the autoclaves a minimum of once a week and with each load containing an implant. The incubator for the biological spores was located, but did not contain any spores.	A154	A 154 - Sterilization a) The corrective action was accomplished Thursday 3/13/08. Corrective action was accomplished by bringing , a 20-year Instrument Processing Technician from BHS and OR Clinical Systems Administrator from BHS with more than 30 years of surgical experience to LTSC. Biological testing was performed on the 2 autoclaves and Steris machine. Scrub Tech 1 was educated about how to perform this testing. Since there was not an incubator available that would hold the biological testing kits, kits were transferred to Barton Memorial Hospital for incubation. Readings were conducted by Support Tech 3, (see attachment E). Support Tech #3 also notified V.P. of Operations at her home. The written results were placed by Scrub Tech 1 in the log books. b) The facility identified others having potential to be affected by the same deficient practice by identifying the staff that was responsible for instrument handling and processing. Support Tech 2 and new employee were identified and will be included in education on proper weekly biological testing. c) On 3/13/08, Scrub Tech 1 spoke to the Steris representative. He ordered an incubator so that biological testing could be done on premises.	3/13/08 3/13/08

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A154	Continued From page 8 The policy titled, "Sterilization Monitoring Biological Indicators and Record Keeping" was reviewed. The policy indicated that biological test will be performed weekly and with all implants to act as a secondary source to assist in evaluating the autoclaves' overall performance. The results of the biological tests will be recorded in the Sterility Assurance Book in the beginning of the day, 24 and 48 hours after incubation. A log book of past biological tests was not located during the survey. The autoclave printouts dating back to 3/4/08 were reviewed. All printouts indicated that the autoclaves had met sterilization parameters. The implant log book was also reviewed. The log book indicated that no patients were implanted with implants sterilized by the facility since 3/4/08. The surgical technician was interviewed about biological testing of the autoclaves. The technician stated that biologicals were run on Mondays and every time an implant was sterilized. The technician reported that an instrument technician, who had recently been terminated on 3/4/08, ran those tests. The technician stated he had not run any biological tests on the autoclaves since the instrument technician left because he did not know how. In the room where the Steris unit was located, a piece of paper titled, "To Run a Steris Cycle" was observed taped to the wall. The rules indicated that biological monitoring needed to be performed every Monday and the results recorded in the Steris Record Book. Biological spores for the Steris machine were not located in the room, nor was an incubator found in the room. The surgical technician was interviewed about	A154	He followed up on it 3/18/08 when it had not arrived. The rep. gave him an ETA of 3/20/08. A decision was made to run the weekly biologicals on Wednesdays rather than on Mondays due to closure of LTSC on holidays that are observed on Mondays. OR Clinical Systems Administrator and Support Tech 1 returned to LTSC on Wednesday 3/19/08 and collected biologicals from the Steris and the 2 autoclaves. The Steris machine biological was incubated at the surgery center and the autoclave biologicals were transported back to BHS for incubation. All readings from these tests were negative and recorded in the respective log books. They educated and demonstrated the procedure to Support Tech 2 at that time. The autoclave biological incubator arrived Tuesday, March 25. Scrub Tech 1 & Support Tech 2 ran the weekly biologicals Wednesday 3/26/08. Article titled Sterilization-Killing the Prehistoric Beast from the March 2008 Journal of The Surgical Technologist was given to all clinical staff members to complete the article as well as the test(see Attachment F)Steris service representative came to LTSC on 3/27/08 and educated all clinical staff on the 2 incubators, Steris, and testing and documentation requirements (see Attachment G). d) Corrective actions will be monitored by daily environmental round checks beginning 3/25/08. The daily logs will be kept for 3 years. Disciplinary action of non-compliant employees will be done if indicated. e) Responsible party for monitoring compliance is LTSC Administrator f) Anticipated date of correction is 3/26/08 after the completion of Scrub Tech 1 and Support Tech 2's training.	3/18/08 3/20/08 3/19/08 3/26/08 3/27/08 3/25/08 3/26/08

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A154	Continued From page 9 biological testing of the Steris unit. The technician reported he had never run a biological test on the Steris unit because he did not know how. The technician further stated that he did not know where the log book was, did not know where the Steris incubator was and did not know where the biological spores were kept. A log book titled "Weekly Steris Sterilization Record" was located in the facility and indicated that the last biological spore that was run on the Steris unit was run on 2/22/08. A review of the operating schedule from 2/28/08 to 3/13/08 revealed the facility performed numerous arthroscopy cases which involved the use of the Steris unit. The Steris printouts were reviewed for that time period and indicated the unit met all sterilization parameters. Severity: 2 Scope: 3	A154		
A161	NAC 449.9902 Emergency Equipment/Supplies 1. An ambulatory surgical center must be equipped with: (a) A cardiac defibrillator; (b) A tracheostomy set; and (c) Such other emergency medical equipment and supplies as are specified by the members of the medical staff. This Regulation is not met as evidenced by: Based on observation and interview on 3/13/08, the facility did not have a tracheostomy set. Findings include: Review of the crash cart revealed that the facility had identified their "trach set" as a pre-packaged device called a "Nu-Trake" Cricothyrotomy device, manufactured by Bivona Medical	A161	A 161- Emergency Supplies a) On 3/13/08, surveyors gave PACU RN the information for a contact to request information on the ordering of a tracheostomy set. When no return calls were received, on 3/21/08 PACU RN contacted BHS Surgery Buyer, to enlist his assistance in ordering the tray. All necessary instruments for a tracheostomy tray were ordered Tuesday, March 25, and will arrive to be put into service Wednesday, March 26. (see Attachment H) b) N/A c) An assortment of trach. tubes were ordered and in place with the tracheostomy tray. All items will remain in place on the crash cart d) N/A e) PACU RN is the responsible party for the accomplishing of the task f) Date of completion 3/26/08	3/26/08

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	NVN1888ASC	A. BUILDING _____ B. WING _____	03/13/2008

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A161	Continued From page 10 Technologies. The manufacture was contacted about the "Nu-Trake" kit. An operation's supervisor stated that the "Nu-Trake" was a cricothyrotomy device and not considered a tracheostomy set. The facility did not have a tracheostomy set. Severity: 2 Scope: 1	A161		
A9999	Final Comments NAC 449.9812 Quality Assurance The facility shall establish and maintain an infection control program designed in accordance with accepted standards of practice to prevent the development and transmission of disease/infection. This Regulation is not met as evidenced by: Based on observation, review of record logs and interview on 3/13/08, the facility failed to ensure the maintenance of their infection control program regarding the biological storage freezer and medication refrigerator. Findings include: The facility had a freezer storing biological implants. The freezer was maintained by Northwestern Bone and Tissue (NWBT). The instructions included: 3) Freezers are monitored by chart recorders 24 hours a day, seven days a week. The wheel charts are changed every Friday at the end of the business day and stapled to a NWBT form. 8) Freezer maintenance will be done in the following manner:	A9999	A 999- Freezer a) The wheel chart was changed Friday 3/14/08 by Support Tech 1. The previous wheel chart was stapled to a North Western Bone and Tissue (NWBT) form. On Friday 3/14/08 frost was removed from the freezer storing the allografts by Support Tech 2 & Scrub Tech 1. The temperature of the refrigerator check was added to the daily rounding sheet so that it will be done every day. b) It was identified that Scrub Tech 1, Support Tech 2 & new employee could all be affected by the deficient practice since they all have sterilization and record keeping responsibilities. c) Off-site training of Scrub Tech 1 & Support Tech 2 occurred in the BMH Reprocessing Department 3/21/08. On 3/26/08, NWBT representative came to LTSC to educate Scrub Tech 1 & Support Tech 2 & the clinical staff about the freezer record keeping (see Attachment I). New employee will spend several days at BMH Reprocessing Department before reporting to LTSC so that her competency on freezer maintenance and recordkeeping can be validated. d) Corrective actions will be monitored by checking the NWBT forms on Fridays to determine that the wheel chart was changed weekly. At that time, the freezer condition will also be noted. Medication refrigerator	3/14/08 3/21/08 3/26/08

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A9999	Continued From page 11 (A) Removal of frost from the interior on the freezer should be done twice a year. Frost should not be allowed to build up around the lid and gasket area, since this could prevent the lid from properly closing. (B) Chart recorder will be changed and documented every week. A review of the Freezer/ Refrigerator Maintenance Log revealed that every month since 9/9/05- 11/29/07, the ice was scraped from the freezer lid and the outside of the freezer was disinfected. This same maintenance log revealed that no disinfection of the freezer or scraping ice formation had occurred since 11/29/07. The surgical technician confirmed that he was not aware that the freezer needed monthly maintenance. Observation of the biological storage freezer revealed that there was approximately one inch of frost built up around the back right corner of the gasket/lid. There was also approximately one and one-half inch frost build-up on the bottom of the freezer compartment, next to the sensor component. There was no evidence in the logs when the interior freezer compartment had been cleaned of frost build-up. The Nursing Supervisor acknowledged that two technicians had been terminated, as recent as 3/4/08. An observation of the temperature monitor graph on 3/13/08, revealed that the temperature monitor graph was supposed to have been changed on 3/3/08. The temperature monitor graph logs revealed these were changed every week by the instrument technician, but had not been done. Review of implant records revealed that the facility implanted three frozen implants from this	A9999	temperature will be checked and documented daily. e) Scrub Tech 1, will be responsible for the accomplishment of the corrective action with the freezer. Support Tech 2 will be responsible for the daily checking of the medication refrigerator temperature. LTSC Administrator will be responsible for monitoring compliance. f) Date of correction was 3/26/08 after NWBT education.	3/26/08

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A9999	Continued From page 12 freezer on 3/6/08. This was three days after the temperature monitor graph should have been changed. A review of the medication refrigerator temperature log revealed that no one checked the temperature from 3/10/08 to 3/13/08. The nursing supervisor and the scrub technician were not aware whose responsibility this was. Severity: 2 Scope: 3	A9999		